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210	7590	01/29/2010	EXAMINER	
MERCK AND CO., INC			DEVI, SARVAMANGALA J N	
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RAHWAY, NJ 07065-0907			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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MERCK AND CO., INC  
P O BOX 2000  
RAHWAY NJ 07065-0907

In re Application of: :  
Anderson et al. :  
Serial No.: 10/564,458 : PETITION DECISION  
Filed: January 12, 2006 :  
Attorney Docket No.: 21569YP :

This is in response to the petition filed December 22, 2009 and the revised petition filed January 5, 2010 under 37 CFR § 1.181, requesting that the finality of the Office action of November 24, 2009 be withdrawn as premature.

## BACKGROUND

The examiner mailed a non-final Office action on December 15, 2008 setting a three month statutory limit for reply. In this action, claims 1-10, 17, 18, 20-25, 27, 29 and 33-46 were pending and claims 1-9 and 33-46 were rejected. Claims 10, 17, 18, 20, 21, 24, 25, 27 and 29 were withdrawn from consideration. Claims 1 and 7 and claims 2-6 and 33-36 that depend therefrom were rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter. Claims 1-9 and 33-46 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 1-13 and 16-18 were rejected under 35 USC 103 (a) as being unpatentable over Foster et al. in view of Christensen et al.

On March 13, 2009, applicants submitted amendments and remarks addressing the rejections set forth in the Office action of December 15, 2008. Claims 47 – 54 were also newly added.

On July 7, 2009, a Notice of Non-Compliant Amendment was issued.

On July 13, 2009, applicants submitted a revised amendment in response to the Notice of Non-Compliant Amendment.

On November 24, 2009, the examiner mailed a final Office action setting a three month statutory limit for reply. In this action, the examiner rejected claims 1-9 and 33-54. Claims 1, 3, 4, 7-9,

33-35, 37-44, 47, 49-51 and 53 were rejected under 35 U.S.C. 112, first paragraph, as lacking written description. Claims 1, 3-9 and 33-54 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

In response thereto, applicants filed a petition on December 22, 2009 under 37 CFR § 1.181, requesting that the finality of the Office action of November 24, 2009 be withdrawn as premature.

On December 21, 2009, the examiner had a telephonic interview with applicants.

In response to the telephonic interview, applicants filed a revised petition on January 5, 2010 under 37 CFR § 1.181, requesting that the finality of the Office action of November 24, 2009 be withdrawn as premature.

## DISCUSSION

The petitions and the file history have been carefully considered.

In the petition filed on January 5, 2010, applicants argue "The November 24, 2009 office action was improperly made final. The November 24, 2009 office action for the first time in the prosecution of the present application provided a written description rejection. The percent identity and number of possible alterations language, upon which the written description rejection was based, was present in claims pending prior to the December 15, 2008 non-final office action. The amendments provided in the response to December 15, 2008 did not necessitate the written description rejection."

Applicants' argument has been carefully considered but it is not persuasive that the final was improper. As explained by the examiner in the interview summary mailed December 21, 2009, the amendment filed July 13, 2009 added many new claims and made significant and scope-changing amendments to almost all examined claims, particularly to claims 1, 3, 5, 7, 8 and 37-46.

Also, due to a number of indefiniteness, ambiguity, and claim language issues as set forth, a reasonable analysis under 35 USC 112, first paragraph, was not possible in the non-final Office action. Note the following few examples:

Example # 1. The open claim language 'comprising' in the original claim 1 being combined with the negative limitation 'one or more additional polypeptide regions .... do not provide a carboxyl terminus .....', when evaluated with the language 'consists essentially of SEQ ID NO: 1' in the dependent claim 5, rendered the scope as well as the metes and bounds of the originally examined claims so indefinite or ambiguous, a sensible analysis under 35 USC 112, first paragraph was not possible. This is because, the specification at lines 14-19 of page 13 expressly defines the limitation 'consisting essentially of' as referring to amino acids being present at the carboxyl or the amino terminus. Note that the base claim 1 excludes carboxyl terminal amino acids 609-645 of SEQ 2, whereas the "consisting essentially" of language in the dependent claim 5 permits the presence of such carboxyl terminal amino acids. These opposing claim languages

rendered the structural composition of the claimed polypeptide and the scope of the claims so confusing that a reasonable analysis under 35 USC 112, first paragraph, was not possible in non-final Office action of December 15, 2008.

Both claims 1 and 5 were amended extensively (and also the dependent claims 3, 4, 8 and 33-46) in the amendment of July 13, 2009, thus eliminating the major indefiniteness issues and now also required the polypeptide immunogen to be 'purified'. These significant amendments eliminated the combined use of the confusing open and closed claim languages, provided some clarity to the structural composition of the claimed product, and made an analysis under 35 USC 112, first paragraph possible only in the second office action. Making such an office action Final is proper.

Example # 2. Although Applicants' petition does not cite/reproduce the amended claim 3, claim 3, originally dependent from claim 2, has been amended extensively, both in terms of scope and dependency. Claim 3, as amended, now depends from claim 1, which itself has been extensively amended as explained above.

Example # 3. The original claim 8, then dependent from claim 1, lacked any recitation or clarity as to the immunospecificity of the broadly recited 'a protective immune response'. Claim 8 was extensively amended including an amendment reciting the specificity of the immune response as now being 'against *S. aureus*' and requiring the polypeptide immunogen now to be 'purified'. Claim 8 was also amended to be an independent claim. The amendments to claim 8 made an analysis under 35 USC 112, first paragraph possible only in the final office action.

Example # 4. The independent claim 7, as rejected in the non-final Office action, included the confusing combination of both the open claim language 'immunogen comprising' and the closed claim language 'immunogen consists of'. This opposing claim language rendered the structural composition of the claimed immunogen and the scope of the claim so confusing that a reasonable analysis under 35 USC 112, first paragraph, was not possible in the non-final Office action. The amendment to claim 7 fixed this problem, provided some clarity to the structural composition of the claimed product, and made an analysis under 35 USC 112, first paragraph possible only in the second office action. Making such an office action Final is proper.

Applicants' arguments have been carefully considered but they are not persuasive as it appears that the new ground of rejection in the final Office action is, in fact, necessitated by amendment.

The following excerpt from MPEP § 706.07 is set forth below:

Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

The examiner's rejection of the claims under 35 U.S.C. 112, first paragraph, as lacking written description was a new rejection considering that the examiner did not originally institute said rejection in the non-final Office action. While new rejections are permitted in final Office actions, such new rejections are only proper under certain circumstances according to the

provisions set forth in the MPEP; those provisions being, either when applicants' amendment to the claims necessitates such a rejection or when an IDS submitted by applicants necessitates such a rejection, see MPEP citation (*Id.*) In the instant case, the claim amendments of July 13, 2009 did alter the scope of the claims requiring a new rejection. In view of the evidence, the final Office action issued November 24, 2009 is not found to be premature nor in error. Consequently, the finality of the Office action will not be withdrawn in favor of applicants.

## **DECISION**

The petition is **DENIED.**

Any new or renewed petition must be filed within TWO MONTHS of the mail date of this decision.

Should there be any questions about this decision please contact Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.



Remy Yucel

Director, Technology Center 1600